REMARKS

Applicant submits that the amendments herein are fully supported in the present specification as filed and add no new matter. Further, the amendments herein address issues that are first raised in the outstanding Office Action, and were not made earlier, because the first indication to Applicant that the present amendments would be needed was in that Office Action (e.g., the comments at page 7 of the outstanding Office Action). Therefore, entry of the present amendment is proper, and is respectfully requested.

Still, if the Examiner continues with the rejections of the present application, it is respectfully requested that the present Amendment be entered for purposes of an appeal.

A Petition for Extension of Time is being concurrently filed with this Amendment. Thus, this Amendment is being timely filed.

Applicant respectfully requests the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

Status of Claims

In the present Amendment, claims 1 and 3 have amended and claims 5-6 have been added Also, claim 2 was previously canceled without prejudice or disclaimer of the subject matter contained therein. Thus, claims 1 and 3-6 are pending.

Support for the amendments to claims 1 and 3 can be found in the present specification at, for instance, page 3, lines 13-19; page 4, lines 13-19; page 10, lines 4-11; page 10, line 17 to page 11; line 1 (e.g., physiochemical interaction); page 12, lines 1-9; the sentence bridging pages 13-14 (e.g., sterilization); page 15, lines 3-8; pages 18-19; page 21, last paragraph; and Example

2 (e.g., drug concentration at the surface of the hydrogel being higher). Support for new claim 5 is found at least at page 10, lines 21-24 and page 12, lines 1-4 of the specification. Support for new claim 6 is seen in the specification at, for example, page 14, lines 2-5. No new matter has been added with these amendments and new claims.

Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicant respectfully requests that the Examiner withdraw all rejections and allow the currently pending claims.

Issues Under 35 U.S.C. § 102(b)

Claims 1-2 stand rejected under 35 U.S.C. § 102(b) as being anticipated by **Ikada *et al.*** (JP 08-325160) (see paragraphs 5-6 of the Office Action).

Also, claims 3-4 stand rejected under 35 U.S.C. § 102(b) as being anticipated by **Chvapil '088** (U.S. Patent No. 4,485,088) (see paragraph 7 of the Office Action).

Applicant respectfully traverses, and reconsideration and withdrawal of these rejections are respectfully requested.

Applicant has taken note of paragraphs **14-15** of the outstanding Office Action, wherein the Examiner responds to Applicant's previous arguments and claim amendments by stating, in general, Applicant is not claiming all argued features and that the prior art still reads upon the claims as pending. More specifically, the Examiner states that sustained release of the drug with control of direction of the drug release is an inherent property, and that the concentration gradient is formed by diffusion (see Office Action at page 7, first two paragraphs).

Applicant respectfully maintains that not all features have been accounted for and the Examiner misunderstands that the concentration gradient is formed by diffusion. In the hydrogel of the present invention, the drug is maintained by physiochemical interaction (which is more clearly recited as seen in the claims herein), and the drug will be released form the gel as the gel is degraded and/or absorbed *in vivo*. On the other hand, in the Chvapil '088 hydrogel, the drug will diffuse within the gel as the drug is released from the surface of the gel. Thus, the concentration gradient is not formed in the gel. Applicant also notes the present specification at, for example, page 10, starting at line 4.

For reasons of record, Applicant respectfully maintains that no gradient of the drug concentration will be made or maintained within the Chvapil '088 gel, and that a gradient of drug concentration will not be made within the gel of Ikada *et al.*

In response to the Examiner's comments in the Office Action at pages 7-8, Applicant respectfully refers the Examiner to the claims as shown herein. Applicant has better defined the way the drug is impregnated or bonds with the gelatin hydrogel to create the concentration gradient.

Further, the "sterile" feature has been added to distinguish from any prior art wherein the sustained release preparation is inserted into a human body (by swallowing) or is placed on the skin, wherein the drug is no longer sterile upon contact with the human body.

Also, the sentence bridging pages 2-3 of the Office Action reads: "Since the gelatin gel will swell and degrade in the presence of water (or body fluid) the concentration of the drug in the gel will change and consequently a concentration gradient of the drug in the gelatin gel will be formed." Applicant respectfully traverses this conclusion as this appears to be speculation or

a personal opinion, or a form of official notice, which improperly accounts for features of the present invention. In this regard, Applicant notes *In re Zurko*, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001) (holding that general conclusions concerning what is "basic knowledge" or "common sense" to one of ordinary skill in the art without specifying factual findings and some concrete evidence in the record to support these findings will not support an obviousness rejection). In any event, as explained above, the drug of the present invention is maintained by physiochemical interaction with the hydrogel wherein Chvapil '088 has a drug that diffuses within the gel.

Based on the remarks herein, reconsideration and withdrawal of all rejections are respectfully requested.

Issues of Obviousness-Type Double Patenting

Claim 1 stands provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/484,023 (referred to as the '023 application hereinafter) (see paragraphs 8-9 of the Office Action).

Also, claim 1 stands provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/528,998 (the '998 application) (see paragraph 10 of the Office Action).

Further, claim 1 stands provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/551,497 (the '497 application) (see paragraph 11 of the Office Action).

In contrast to the present invention, the claim 1 of each of the cited '023, '998 and '497 applications does not render claim 1 of the present application as obvious since those claims of

the '023, '998 and '497 applications do not have a drug concentration gradient as achieved by the present invention. The drug entrapped within the '023 / '998/ '497 gelatin moves via diffusion (similar to the cited Ikada *et al.* reference mentioned above). But in the present invention, the direction of drug release is controlled and the drug is entrapped in the gel such that it will not move within the gel.

Therefore, reconsideration is respectfully requested, especially in light of the claim amendments and comments herein. As mentioned, the present invention is directed to a sustained-release preparation which comprises a drug and a gelatin hydrogel. The present invention is characterized in that a concentration gradient of the drug is formed within the hydrogel, which enables a larger amount of drug to be released from the drug-rich side of the hydrogel versus the drug-lean side of the gel, whereby the direction of drug release can be controlled. Also in the present invention, the drug is impregnated into said gelatin hydrogel through a surface thereof and is maintained in said hydrogel by physiochemical interaction. Finally, the concentration gradient being higher at said surface than in other parts of said hydrogel. The present invention is patentably distinct over the cited gelatin of the '023 / '998/ '497 applications.

Thus, these provisional rejections have been overcome. Reconsideration and withdrawal of these rejections are respectfully requested.

In the alternative, Applicant requests the Examiner to hold these rejections in abeyance (as they are provisional) until this application or the cited application(s) issues as a patent.

Conclusion

A full and complete response has been made to all issues as cited in the Office Action. Applicant has taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicant respectfully requests that a timely Notice of Allowance issue for the present case.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez (Reg. No. 48,501) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By _____
Gerald M. Murphy, Jr.
Registration No.: 28,977
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road, Suite 900 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicant